UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,634	12/09/2005	Leon Carlock	28928.0010	6748

30827 7590 09/19/2006

MCKENNA LONG & ALDRIDGE LLP
1900 K STREET, NW
WASHINGTON, DC 20006

EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/539,634	CARLOCK ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 4, 8, drawn to the polypeptides of SEQ ID NOs:6 and 12.

Group II, claim(s) 5, 9, drawn to the polypeptides of SEQ ID NOs:8 and 16.

Group III, claim(s) 6, drawn to the polypeptide of SEQ ID NO:18.

Group IV, claim(s) 15 (in part), 18, 28 (in part), 30 (in part), 31 (in part), drawn to the polynucleotides of SEQ ID NO:5 and 11

Group V, claim(s) 15 (in part), 19, 28 (in part), 30 (in part), 31 (in part), drawn to the polynucleotide of SEQ ID NO:9 and 15

Group VI, claim(s) 16 (in part), 28 (in part), 30 (in part), 31 (in part), drawn to the polynucleotide of SEQ ID NO:7.

Group VII, claim(s) 16 (in part), 28 (in part), 30 (in part), 31 (in part), drawn to the polynucleotide of SEQ ID NO:13

Group VIII, claim(s) 17, 28 (in part), 30 (in part), 31 (in part), drawn to the polynucleotide of SEQ ID NO:17.

Group IX, claim(s) 32-40 and 44, drawn to cells that is modified to comprise a vector.

Group X, claim(s) 46-49, 52-54 (all in part), 55, drawn to a method of treating a demyelinating disease/disease of oligodendrocyte using the polypeptide of SEQ ID NO:6

Group XI, claim(s) 50, 51, 56 (all in part), drawn to a method of treating a demyelinating disease/disease of oligodendrocyte using the cells comprising a DNA sequence of SEQ ID NO:5.

Group XII, claim(s) 50, 51, 56 (all in part), drawn to a method of treating a demyelinating disease/disease of oligodendrocyte using the cells comprising a DNA sequence of SEQ ID NO:9.

Group XIII, claim(s) 52-54 (all in part), drawn to a method of stimulate neural stem cell/oligodendrocyte survival in vitro using the polypeptide of SEQ ID NO:6.

Group XIV, claim(s) 57-58, drawn to a method of regulating/inhibiting the production of PLP/DM20 in a subject by administering to the subject the polypeptide of SEQ ID NO:8.

Group XV, claim(s) 59-60 (all in part), drawn to a method of regulating/inhibiting the production of PLP/DM20 in a subject by administering to the subject the cells comprising the polynucleotide of SEQ ID NO:7.

Group XVI, claim(s) 59-60 (all in part), drawn to a method of regulating/inhibiting the production of PLP/DM20 in a subject by administering to the subject the cells comprising the polynucleotide of SEQ ID NO:13.

2. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The PLP recited in claim 1 is known in the art and also disclosed by Folch, J. et al. (1951. JBiol Chem. 191: 807-817) and Wolfgram, F. (1966. J. Neurochem. 13: 461-470) as described by Applicant on p.1 of the specification. Thus, 1st claimed invention was found to have no special technical feature that defined the contribution over the prior art. Since the 1st claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed inventions. Thus, Applicant's inventions do not have a special technical feature when view over the prior art, they do not have a single inventive concept and so lack unity of invention.

Group I is drawn to a technical feature of the polypeptides of SEQ ID NOs:6 and 12.

Group II is drawn to a technical feature of the polypeptides of SEQ ID NOs:8 and 16.

Group III, claim(s) 6, drawn to a technical feature of the polypeptide of SEQ ID NO:18.

Group IV is drawn to a technical feature of the polynucleotides of SEQ ID NO:5 and 11

Group V is drawn to a technical feature of the polynucleotide of SEQ ID NO:9 and 15

Group VI is drawn to a technical feature of the polynucleotide of SEQ ID NO:7.

Group VII is drawn to a technical feature of the polynucleotide of SEQ ID NO:13

Group VIII is drawn to a technical feature of the polynucleotide of SEQ ID NO:17.

Group IX is drawn to a technical feature of cells that are modified to comprise a vector.

Group X is drawn to a technical feature of a method of treating a demyelinating disease/disease of oligodendrocyte using the polypeptide of SEQ ID NO:6

Group XI is drawn to a technical feature of a method of treating a demyelinating disease/disease of oligodendrocyte using the cells comprising a DNA sequence of SEQ ID NO:5.

Group XII is drawn to a technical feature of a method of treating a demyelinating disease/disease of oligodendrocyte using the cells comprising a DNA sequence of SEQ ID NO:9.

Group XIII is drawn to a technical feature of a method of stimulate neural stem cell/oligodendrocyte survival in vitro using the polypeptide of SEQ ID NO:6.

Group XIV is drawn to a technical feature of a method of regulating/inhibiting the production of PLP/DM20 in a subject by administering to the subject the polypeptide of SEQ ID NO:8.

Group XV is drawn to a technical feature of a method of regulating/inhibiting the production of PLP/DM20 in a subject by administering to the subject the cells comprising the polynucleotide of SEQ ID NO:7.

Group XVI is drawn to a technical feature of a method of regulating/inhibiting the production of PLP/DM20 in a subject by administering to the subject the cells comprising the polynucleotide of SEQ ID NO:13.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept because the composition and structural/functional features are different within these Groups. The use and results from Groups I-XVI are different. They do not share a common corresponding technical feature. Since they do not share a common technical feature, they do not have a single inventive concept, thus lack unity of invention.

3. Claims1-3, 7 and 41 link(s) inventions I, II and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3, 7 and 41. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Claims 10-14, 20-27, 29, 30, 42 and 43 link(s) inventions IV, V, VI VII and VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 10-14, 20-27, 29, 30, 42 and 43. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional

statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

i. If any one Group from Groups IV-VIII, XI-XII, XV-VI is elected, Applicant is required to elect one species of vector selected from A) PLP-GFP/DM20-GFP; B) PLP-GFP/DM20-GFP Tet-On; C) PLP-GFP/DM20-GFP M1L; D) PLP-GFP/DM20-GFP M1L/M205L; E) PLP-GFP/DM20-GFP M1L/M234L; G) PLP-GFP/DM20-GFP M1L/M205L/M234L; H) PLP-GFP/DM20-GFP Pro-; I) JPLP-GFP/JDM20-GFP; J) JPLP-GFP/JDM20-GFP M1L; K) JPLP-GFP/JDM20-GFP M1L/M205L; L) RshPLP-GFP/RshDM20-GFP M1L; M) PLP-GFP/DM20-GFP M1L/K268R; N) PLP-GFP/DM20-GFP M1L/K275R; O) PLP-GFP/DM20-GFP M1L/K268R/K275R; P) PLP-GFP/DM20-GFP M1L/R272K; Q) 205M-CMV/234M-CMV; R) 205M-His-CMV/234M-His-CMV; S) 205M-BsKS+/234M-BsKS+; T) 205M- His-BsKS+/234M-His-BsKS+; or U) 205M-ET-14b/234M-ET-14b as

recited in the claims 28 and 30. Currently, claims 10, 27, 29, 32, 34, 42, 43, 44, 50, 51, 56 and 59 are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The composition and structural features are different in different SEQ ID NOs and vectors. Therefore, these species do not share a common technical feature and so lack unity of invention.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-XVI and a single species from group i that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should

applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
August 30, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER